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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,055

08/21/2003

Douglas A. Devens JR.

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

08/18/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/645,055

Applicant(s)

DEVENS ET AL.

Examiner

VICTORIA P. CAMPBELL

Art Unit

3763

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-13, 15-26, 39-42 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11, 13, 15, 16, 18-26 and 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 10, 12, 17 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/14/10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This is the second Office Action following the second Request for Continued

Examination based on the 10/645055 application filed August 21, 2003. Claims 1-5, 8, 10, 12, 17, and 48 are currently pending and considered below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
3. Claims 1 and 48 have been amended to recite limitations which compare the thickness of the first portion waist portion to the first portion cone portion and citation is given to Figure 2 for support. However, the examiner notes that the specification with regard to Figure 2 only describes the relationship of thickness between the first portion body portion and the first portion cone or waist portions (Page 5, lines 14-16). No further discussion of the first portion waist portion's thickness is given with reference to the first portion cone portion's thickness. Regarding applicant's reliance on Figure 2 to show that the first portion waist portion has a thickness less than that of the first portion

cone portion, the examiner notes that no indication has been given that the drawings submitted by applicant are to scale, and therefore no specific size relation can be gleaned from the drawings. For purposes of examination, the references to the thickness of the first portion in the waist portion in comparison to the thickness of the first portion of the cone portion have been treated as references to the thickness of the first portion waist portion relative to the first portion body portion as supported by the specification as filed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-5, 8, 10, 12, 17, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,364,856 B1 to Ding et al.

Regarding claims 1-3, 8, 10, and 12 Ding et al disclose a medical device comprising a balloon (3) comprising a first portion having a first length (2), and a second portion disposed on the first portion having a second length (4), wherein the second portion defines an outer surface of the balloon; wherein the first portion varies in thickness along the first length and the second portion varies in thickness along the second length (Figs. 2a, 2b; see right hand side), wherein the balloon has a waist portion, body portion, and a cone portion and wherein the first portion has a greater thickness at the body portion than at the cone portion (Fig. 2b; the body portion of the first portion is thicker than the tapered portion of the right-hand cone portion; see Fig. 2b reproduced below for clarification).

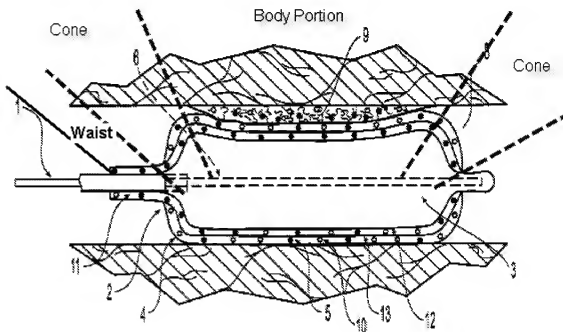


Fig. 2b

Ding et al further disclose that the first and second portions have different compositions (the first portion is a reservoir, the second is a sponge material), that the second portion

is disposed substantially entirely on the first portion, that the thickness of the first and second portions is generally constant in the cone portion (the tapering of the portions takes place only at the most extreme end of the cone portions, and therefore the thickness is maintained along substantially the entire length), and that the first portion extends substantially the entire length of the balloon (Figs. 2a and 2b). Ding et al fail to explicitly teach or disclose that the thickness of the waist portion of the first portion is less than the thickness of the body portion of the first portion. However, the examiner notes that at the time of invention, it would have been obvious to one having ordinary skill in the art to reduce the thickness of the first portion along the waist portion in order to reduce the profile of the balloon.

Regarding claims 4 and 5, Ding et al do not explicitly teach or disclose that the first and second portions have different hardness or that the second portion is softer than the first portion. However, these properties of the first and second portions are either inherent or obvious to one having ordinary skill in the art at the time the invention was made, as material selection from those commonly used in the art is considered obvious. In addition, because the first and second portions taper sharply at the end of the cone portion, the examiner believes this would impart additional flexibility to the cone portion because, in general, when the thickness of a material is decreased, its flexibility is increased.

Regarding claim 48, Ding et al teach a balloon catheter comprising a catheter shaft (1) having a longitudinal axis; a balloon (3) comprising an inner layer (2) and an outer layer (4); wherein the balloon has a proximal waist attached to the catheter shaft,

a proximal cone portion extending radially outward from the proximal waist, a body portion extending substantially parallel to the longitudinal axis of the catheter shaft, a distal cone portion extending radially inward from the body portion, and a distal waist attached to the catheter shaft (Fig. 2a; the examiner notes that the distal waist portion has been interpreted as the point of attachment of the distal portion of the balloon to the catheter and is not marked in the above drawing). Ding et al do not explicitly teach that the inner layer has a first thickness along the proximal waist; a second thickness along the proximal cone portion; and a third thickness along the body portion; wherein the third thickness is greater than either the first and second thicknesses. However, the examiner notes that at the time of invention, it would have been obvious to one having ordinary skill in the art to provide different thicknesses of the inner layer in the waist and cone portions to allow for a reduction in balloon profile for delivery and removal.

Response to Arguments

7. Applicant's arguments filed June 14, 2010 have been fully considered but they are not persuasive.
8. Regarding applicant's argument that the limitations rejected under 35 U.S.C. 112, first paragraph, are enabled in the specification and drawings, namely Figure 5 and page 6, lines 27-29, the examiner notes that these descriptions are drawn to a non-elected embodiment and there is no evidence to suggest that the applicant had the possession of the device of the elected embodiment (Figure 2) in combination with the

features of the non-elected device of Figure 5 at the time of invention. As such, the examiner has maintained the above rejection.

9. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The examiner notes that, at the time of invention, it would have been obvious to one having ordinary skill in the art to reduce any and all dimensions of a balloon, to not only allow for easier passage through the vessels, but to additionally both provide a smoother transition between portions of the inflated or deflated balloon, and to allow the balloon to access more narrow vessels of the vasculature.

10. Regarding applicant's argument that the rationale provided by the examiner teaches away from modifying the thickness of the balloon at the waist portion, the examiner disagrees and notes that teaching an alternative method is not tantamount to a teaching away.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763